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10/599,779	06/28/2007	Thienna Ho	70063.00004	4440
58688 7590 03/24/2011 CONNOLLY BOVE LODGE & HUTZ LLP P.O. BOX 2207 WILMINGTON, DE 19899			EXAMINER YU, GINA C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/599,779
Filing Date: June 28, 2007
Appellant(s): HO, THIENNA

JONATHAN JAECH
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on November 1, 2010 appealing from the Office action mailed on May 28, 2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 4-6, 9-11, 13, 15, 17 and 19 are pending and rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 4296130	HERSCHLER	10-1981
WO 94/05279	SALIM	03-1994

Webster's Ninth New Collegiate Dictionary (1991), Merriam-Webster Inc., p. 296.

Timmons, H., "Telling India's modern women they have power, even over their skin tone," New York Times, May 30, 2007, page C5 (printed from ProQuest, on 5/19/2010).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 9-11, 13, 15, 17, 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Herschler (US 4296130) in view of Webster's Ninth New Collegiate Dictionary (1991) and Salim (WO 94/05279).

Herschler teaches methyl sulfonyl methane (MSM) can be included in a cosmetic or other preparations applied to the skin, and beautifies the complexion, improves the condition of the scalp and hair and help to make the body of the user more flexible and comfortable. The reference also teaches MSM can be administered orally. See col. 2, lines 18 – 46. The reference teaches MSM is inert to the chemistry of the body.

Webster teaches the term "complexion" of skin refers to the hue or appearance especially of the face, as in "a dark complexion". See p. 269, second col. complexion. The usage of the term to denote skin tone is also seen in applicant's specification, p. 5, second paragraph, "a daily maintenance of facial skin tone, that is, to maintain a lighter facial complexion after a desired amount of skin lightening has already been achieved".

Herschler does not teach the dosage of MSM oral administration as required by the present claim.

Salim teaches a method of treating and improving skin condition by administering methyl sulfonyl methane and a sulfur-containing amino acid. The reference teaches the composition may be administered topically, orally or parenterally. See p. 7, first paragraph. The reference teaches the oral dosage unit contains from 100-500 mg of each of methyl sulfonyl methane and amino acid, and given once or more daily at intervals of from 2-8 hours, most preferably every 6 hours (e.g., 300-1,500 mg taken thrice daily at 6 hour interval or more at 2 hour interval). The reference also teaches

topical administration comprising at least 0.5 % w/w of each of the active ingredients, preferably 5 % methyl sulfonyl methane and 2 % cysteine or methionine. See p. 5, first full paragraph. The reference teaches the improvements in skin condition includes combating aging of skin, protection against environment, providing suncreening effects, enhancing the healing of wounds, inflammation, fissures, and maintenance of its vitality, smoothness, firmness and texture. See p. 3, bridging paragraph. The reference indicates , for example, a topical formulation of Example 1.D were applied twice daily for 6 months then once daily for 18 months, resulting in significant improvement in the skin's smoothness, firmness, and wrinkle reduction. See p. 18, second full par.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the present invention that the Herschler method of administering MSM to human subjects would bring about changes to, and/or improve, the color and skin tone and/or overall appearance of the skin because the reference teaches MSM "beautifies complexion" of the skin, and the Webster dictionary indicates that complexion refers to the color or appearance of skin in cosmetic art. Thus applicant's claim of development of "a skin tone noticeably lighter than the person's natural skin tone" by administering MSM to the patient would naturally flow from practicing the Herschler method, which would have been obviously observed by one of ordinary skill in the art.

Furthermore, orally administering MSM with the amount and dosage within the present claim limitation would also have been obvious in view of the teachings of Salim because 1) Herschler teaches MSM is nontoxic and inert to the chemistry of the body; and 2) Salim provides general teachings of the oral dosage of MSM to obtain cosmetic

effects. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, Herschler teaches administration of MSM beautifies complexion of the skin and Salim teaches 1,500 mg of MSM may be orally taken thrice daily at 6 hour interval or more at a more frequent interval to obtain various skin conditioning benefits. Thus the prior arts sufficiently provide conditions of the presently claimed invention for a skilled artisan to work with, and discover the optimum or workable ranges by routine experimentations. In view of the combined teachings of the references, the present claims are viewed an obvious variation of the prior art use of MSM to improve skin complexion.

(10) Response to Argument

The present method is directed to a method of orally administering MSM to any human subject 133 mg of MSM per kg of body weight for more than three months. MSM is an old and well known cosmetic agent, whose effects include improvement of "complexion" the skin. Oral administration of MSM up to 300-1,500 mg taken three times daily at 6 hour interval or more at 2 hour interval per day is also known. According to applicant's own disclosure, "200-5000 mg of MSM per day" is sufficient to observe change in skin color in the subject. See p. 5, bridging par. The Examiner

respectfully points out that the present method is not intended for any specific group of subjects. Any individual who practices Herschler's or Salim's method and takes MSM in such amount will experience the claimed skin color change.

A. Oral administration of MSM according to prior art necessarily results in the claimed skin lightening method; the claimed skin lightening effect is expected.

Appellant asserts that the rejection "relies heavily" on Herschler's disclosure that administration of MSM to human is known to "beautify the complexion" of the subject. Examiner respectfully disagrees with such assessment of the prosecution history. The rejections are based on the combination of the cited references, and in this case, Salim's disclosure of oral administration of the same compounds to human subjects and the teachings of both Herschler and Salim that MSM are known to bring about aesthetic changes to skin must be also accounted for. The reason that the Herschler disclosure has been discussed disproportionately through out the prosecution was due to appellant's own effort to urge the Office to accept an interpretation of the term "complexion" in a certain way. No where in the rejection suggests that the teachings of other references should be given less weight or consideration.

Appellant and declarants assert the term "complexion" as used in Herschler specifically excludes skin color and tone. The argument is unpersuasive and not convincing. The usage of the term to mean skin color or tone is notoriously well known in both cosmetic art and in general public. Herschler does not define the term otherwise. More notable is appellant's own use of the same term in the specification to

mean skin color without any ambiguity or need for a definition of the term:

MSM may also be compounded with known cosmetic compositions such as foundation, lipstick, or powder. For example, a relatively low concentration of MSM may be provided in a foundation for use as a daily maintenance of facial skin tone, that is, to maintain a lighter facial **complexion** after a desired amount of skin lightening has already been achieved using a higher concentration of MSM in a topical preparation as disclosed herein. ...Light olive (skin type III) observed in total body **complexion** . . .

See spec. p. 5, first full paragraph; Table II, Result column.

Appellant and declarants argue that the phrase "beautify complexion" should be defined in Herschler as to provide a softer, smoother texture and more youthful appearance of the skin. Particularly, appellant argues that no other meaning should be given to the term "complexion". Examiner respectfully disagrees. Nowhere in Herschler such uncommon definition of the term is found. Especially in this case, when appellant has given the common meaning of the term "complexion" to mean skin color, it is unreasonable to exclude such commonly understood meaning of the well-known term. Appellant's arguments and declarant's statements are based on a hindsight, biased and intentional interpretation at best. Examiner asserts that the objective interpretation of the term "complexion" that is in accord with the record is skin color and tone.

Appellant's statement "[t]he Final Action does not argue that any dose regimen taught by Herschler would inherently result in lightening of skin tone" is incorrect. The rejection fully discussed the Herschler's disclosure that administration of MSM to human subject according to the prior art method will result in the changes of skin color or tone.

B. No criticality of appellant's dose is shown.

Appellant argues that the Office has erred in citing Salim as disclosing appellant's claimed dosage. Appellant then asserts that the oral dose of MSM as disclosed in Salim ranges only 100 to 500 mg at intervals of 2-8 hours, and a maximum dose of MSM would be in the range of 1500-2000 mg per day (500 mg three or four times daily), with the maximum dosage of 33-44 mg/kg/day, for a 45 kg adult. In response, examiner asserts that general condition for a person of ordinary skill in the art to manipulate the dosage of MSM are given in the prior arts. Herschler teaches administration of MSM beautifies complexion of the skin and Salim teaches 1,500 mg of MSM may be orally taken thrice daily at 6 hour interval or more at a more frequent interval to obtain various skin conditioning benefits. Examiner also points out that no criticality of appellant's dosage is shown in the record. According to applicant's own disclosure, "200-5000 mg of MSM per day" is sufficient to observe a change in skin color in the subject. See p. 5, bridging par. Thus, the claimed dose of MSM is an obvious manipulation of the prior art.

Appellant also asserts a skilled artisan would not have been motivated to increase the disclosed MSM dosage because the decreased amount was already known to be effective for "all known cosmetic and therapeutic applications". Appellant asserts that there is no suggestion of using higher doses of MSM for any beneficial effect. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

by routine experimentation.” See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is well settled that determining the optimal value of a result-affecting variable is normally obvious, unless the claimed process condition produces an unexpected result. See Pfizer Inc. v. Apotex Inc., 480 F.3d 1348, 1368-69 (Fed. Cir. 2007). In this case, prior arts teach myriads of cosmetic and health effects of MSM; MSM has no known toxicity even in at a high dose. Given such knowledge, manipulating the dose to achieve the optimal cosmetic result would have taken only ordinary skill in the art. Appellant has not shown any criticality of the claimed dose in general population.

C. No unexpected result is shown.

Appellant also relies on declarants’ opinion testimonies to assert that the claimed invention was not predicted at the time of the invention. It is well settled in patent law that any claim of unexpected results must be supported by objective, factual evidence; in this case, no such evidence is present to support appellant’s position. Declarant’s only source of finding “unexpected results” is that the term “complexion” as used in Herschler should not be interpreted to mean skin color, which is contrary to what a person of ordinary skill in the art would have interpreted.

Furthermore, as indicated above, appellant has disclosed that administration of 200-5000 mg per day would be sufficient to observe skin color change; there is no limit on the user population in the present claims. Thus any individual who is administered MSM according to Salim would necessarily experience skin color change.

Examiner respectfully submits that a *prima facie* case of obviousness has been properly made, and appellant has failed to show any unexpected results within the scope of the claimed invention.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/GINA C. YU/
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